

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN ACADEMY OF
PEDIATRICS, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 8:18-cv-883-PWG

PROPOSED ORDER

Upon consideration of Defendants' motion for clarification, it is hereby

ORDERED that the motion is **GRANTED**; and it is

FURTHER ORDERED that the remedial order entered by the Court on July 12, 2019, ECF No. 127, is **CLARIFIED** by adding the following paragraph:

"5. This order does not restrict the FDA's authority to enforce the premarket review provision against deemed products, or categories of deemed products, before the close of either the 10-month application submission period or the FDA application review period described above."

SO ORDERED.

Dated: _____

8/12/19



PAUL W. GRIMM
United States District Judge